you're comfortable with that for the combined one.

DR. GLOWACKI: Is this the point where I can suggest adding some terms into that?

DR. ROBERTSON: Sure.

DR. GLOWACKI: It would be "Ceramic, polymeric or composite bone-filling devices for use in filling periodontal defects or as an extender of fresh autogenous bone graft in filling other non-load-bearing intraosseous defects," and recommend that Class II.

DR. ROBERTSON: Mark?

DR. PATTERS: Historically, I've almost always agreed with Dr. Glowacki until today. I'm uncomfortable combining the filling of periodontal defects, which involve, as shown in the grid, a definition regarding reduction of pocket depth and gain in clinical attachment and gain in alveolar bone height--that is a very specific indication--combining that with using it as an extender to fill some bone hole somewhere else where attachment and pocket depth and such are not issues.

DR. GLOWACKI: Well, that's what I'm getting at, really. Is that definition of the periodontal defect so helpful?

DR. PATTERS: Oh, it is for me.

[Laughter.]

DR. GLOWACKI: But from the device point of view--

DR. PATTERS: It's not just a hole; it's a very special hole.

DR. ROBERTSON: And how does that relate to your concern about the additional wordage having to do with extender?

DR. GLOWACKI: Well, see, what I'm trying to have is as few definitions as possible. But I feel that we may have missed--and I don't know how meaningful it is--what really the use is out there in the community for the ceramics and the polymeric materials as extenders of fresh autogenous bone in filling defects outside of oral surgical indications.

Dr. Stephens, as the oral surgeon on the panel, can you illuminate us on that?

DR. STEPHENS: Well, I'm not sure of the uses outside of oral and maxillofacial surgery, but certainly there's a wide group of indications within oral surgery in both weight-bearing and non-weight-bearing locations.

DR. GLOWACKI: In terms of the weight-bearing, then, do you feel that there's enough information out there to really define how much of it you would mix with the fresh autogenous bone to satisfy the weight-bearing demand?

DR. STEPHENS: I don't know that there's enough

information to be specific about the mixtures. I think they are kind of all over the place as far as the amounts.

DR. GLOWACKI: But I'm remembering the presentations that Dr. Phillip Boyne had given to us, and he certainly championed that use initially and I think still uses the fresh autogenous bone with these materials in some of those trays for, you know, those massive reconstructions. And I think because so many of the uses now are for dental applications that are smaller defects, but are not being used with this, we sort of lost the focus on that, and that's why I wanted to get back to that.

And maybe it needs to have its own separate definition to satisfy Dr. Patters, but I was just trying to be more economical in that. But that's the reason that I really feel it needs to be recommended for a Class II. That's what I was driving at.

DR. STEPHENS: Yes. I agree with--I think that the amount of information available using them together is more than adequate. I think the problem that Mark has--if I understand it, combining the two is the problem. I think that separately, I don't think there's a problem at all. I think the problem is--putting two together in this definition, I think, is the problem.

DR. PATTERS: Because I see them as very separate

indications, not the same indication.

DR. STEPHENS: Yes.

DR. ROBERTSON: Yes. I guess I would agree with Mark that I don't think it fits in periodontal defect.

DR. GLOWACKI: Well, there are two different sub-specialties using them in that, but from the material point of view, and perhaps even from the manufacturers' point of view, and certainly from a biological point of view, it would make sense for me to lump them together, but I can appreciate the specialties concerns.

DR. PATTERS: Well, for me, the events involved in the healing of periodontal defect are very different than the events involved in healing of an osseous defect that is bound totally by load.

DR. GLOWACKI: With fresh autogenous bone?

DR. PATTERS: Yes. It doesn't involve connective tissue attachment.

DR. ROBERTSON: And, indeed, I mean there are great risks in placing fresh autogenous bone in a periodontal defect, whether it's expanded or unexpanded. As a matter of fact, the sequelae are so severe that we don't, in general, do it, and that is you essentially lose the root surface against which you place the bone. So it doesn't fit very well.

DR. GLOWACKI: Okay.

DR. ROBERTSON: I don't know where to put it, but I don't know that we can put it here.

DR. GLOWACKI: When the time comes, let me know to make a recommendation for another definition.

DR. ROBERTSON: Okay.

DR. BOUWSMA: Mr. Chairman, what is the purpose for separating out completely the different indications?

DR. ROBERTSON: Well, this is--you mean between periodontal defects and non-load-bearing and load-bearing, as we have them now?

DR. BOUWSMA: I mean all of these indications, and let me--I head several things. It would lead almost to something like the following: a ceramic or polymeric or composite material for use in filling oral osseous defects, such as periodontal defects, bone defects, in non-load-bearing situations--alveolar defects, tooth extraction sites. I mean, they're all osseous defects and we're just focusing, then, on the specific type of indication.

DR. ROBERTSON: Yes, and unfortunately my sense is that the classification will change with the indication.

DR. BOUWSMA: I mean, that's what we have chosen to do, but maybe it doesn't have to.

DR. ROBERTSON: Well, we'll find that out. I

mean, if you lump them altogether, my guess is that it's going to make the classification--for example, filling periodontal defects with ceramic bone very well might be a II, but filling extraction sites with ceramic bone very well might be a III.

DR. GLOWACKI: Dr. Robertson?

DR. ROBERTSON: Yes?

DR. GLOWACKI: I agree with Dr. Bouwsma. None of this makes any sense unless somebody is going to be making a recommendation for a different classification. So can we get a sense of that now, because I think that helps us?

DR. ROBERTSON: Well, that's where exactly I was going. We were trying to make sure we were happy with periodontal defect, load-bearing and non-load-bearing things as we had generally--as I have generally read them and that you're going to write them definitively for us eventually here. And we got sidetracked with the extender business, and where I thought we needed to go now was exactly where you want to go, and that is were we comfortable with the combination of 1(a) and 2(a) that we have now, which now are 1(a), periodontal defects. Both before were recommended as Class II, and I was going to now raise the question are we comfortable with that Class II.

I see a lot of nodding, so am I--

DR. PATTERS: Yes.

DR. ROBERTSON: Good, very well. We'll vote on it formally, but I wanted to make sure we--so in the non-load-bearing 1(b), which is the combination of 1(b) and 2(b) into the non-load-bearing, it was Class III and Class III. Are we comfortable with that classification? Julie, you'll have to help us here.

DR. GLOWACKI: I am.

DR. ROBERTSON: Around the room, is anybody uncomfortable with that? You're uncomfortable?

DR. NORMAN: Yes.

DR. ROBERTSON: And what would you like to argue for?

DR. NORMAN: II.

DR. ROBERTSON: Class II. So, Dr. Norman, would you tell us why you would prefer Class II rather than Class III?

DR. NORMAN: I don't see any specific difference between the situation in (a) and (b). The only difference I see is there is not enough scientific data, but that well can come out in the application for Class II and you have to provide scientific data to support it, and the standards would be the same.

DR. ROBERTSON: Dr. Bouwsma?

DR. BOUWSMA: I think that's what I was driving at just a minute ago. I see the situations as exactly the same. It would be up to the particular company submitting to the agency to provide various safety and efficacy information, and the agency then would make decisions based on that. But it looks like each of these situations is, you know, just slightly different, but basically all osseous defects.

DR. ROBERTSON: Well, I'll now turn to Dr. Glowacki who, I think, will disagree with this.

DR. GLOWACKI: Well, the reviews of all of the information that the panel has been provided, in my opinion, provide no meaningful data on effectiveness, first of all, of the use of these materials alone in those indications. And there's insufficient information with regard to the sizes of the defect, the ages of the patient, the precise uses that have been recommended as indications. I just don't think there's data on effectiveness in some, and I can't see, based upon all the information that's available, that special controls could be defined to indicate where they would be safe and effective.

DR. ROBERTSON: And, in fact, that--

DR. NORMAN: I agree that this is the situation, with the exception that I think special controls are

appropriate in defining the value of using a particular material in a particular way.

DR. ROBERTSON: Well, the argument of the sessions I have attended has been as Dr. Glowacki just summarized them. She argues only that for periodontal defects, there has been sufficient data published and presented and reviewed by the panel to have confidence that special controls will, in fact, make her comfortable in terms of safety and efficacy, and that view was shared by a number of the members of the panel. Conversely, in non-periodontal osseous defects, the information that was available was not sufficient to be able to know that, and therefore a Class III classification was voted for.

DR. NORMAN: But if the data is presented in a Class II situation before FDA where they show that the material is effective, I can't see that the lack of information cannot be applied in the classification to date.

MS. JEFFRIES: May I say something?

DR. ROBERTSON: Yes.

MS. JEFFRIES: In order for the panel to put something into Class II, they have to come up with specific special controls. If you can't come up with a control now, you know, we can't do it later. This can always be reclassified, but you have to specify any special controls.

If you can't come up with it, you can't put it in Class II.

DR. ROBERTSON: As a matter of fact, we have to put it in Class III, as I understand it, if we're unable--

MS. JEFFRIES: Yes, if you are unable to come up with a special control. That's right.

DR. ROBERTSON: Yes. Dr. Patters?

DR. PATTERS: But could not a special control be controlled clinical trials?

MS. JEFFRIES: It could be. You would have to specify something like a guidance document that delineates well-controlled clinical studies, you know, as being something that has to be applied to 510(k).

DR. ROBERTSON: Yes?

DR. ULATOWSKI: But the clinical studies in the sense of special controls relates to the ability to determine substantial equivalence, substantial equivalence in performance of one product to another. It's not there to determine safety and effectiveness after the fact that Dr. Norman suggests.

MS. JEFFRIES: If I can elaborate on that, in order to find something substantially equivalent, you have to compare it to something that's already legally on the market. Here, there's obviously nothing to compare it to where you could come up with a special control.

DR. ROBERTSON: And the consequence of classifying one of these in Class III is, in fact, to require clinical studies.

MR. ULATOWSKI: For the purpose of determining safety and effectiveness of the product because you do not know at this point in time what the hazards and risks are of the product.

DR. ROBERTSON: That's what Class III does for us, I think, which was the rationale.

DR. NORMAN: But there are studies that show bone augmentation in other sites.

MS. JEFFRIES: But has it been promoted for that commercially? That's what you're classifying. Something has to already have been on the market for that purpose.

DR. ROBERTSON: I pretend no expertise in this area and never have. I simply--

DR. NORMAN: I would agree with you, in my case.

DR. ROBERTSON: The group that reviewed the available data, both provided by the companies and in literature search, concluded that for this specific indication there was insufficient information for the panel to be able to recommend Class II with special controls. And I think if we know something new--and, for example, for the membranes we very well may know something new--then I think

we can change that. I guess I'd have to hear some new data in order to change my mind.

DR. GLOWACKI: Mr. Chairman, having this grid and having everything narrowed down enabled me to go back to all of the documentation and information that was provided, and look at each of the separate classes of materials, the resorbables and non-resorbables, synthetics, and all of those different--and really focus in on it. And what I came away with after reviewing the information is that the best data that are out there available to us is on the use of these materials as extenders of fresh autogenous marrow.

There's no question in my mind about effectiveness and safety, and beyond that when one looks at the reports, in my opinion, on the use of the materials alone, the data are on very peculiar groups of patients, patients under the age--there were studies there under the age of 28, defects that are 1.5 centimeters or smaller, and it's very, very limited information. And I spent hours and hours going back and reviewing that so that I could write a special control and I was not able to do that for this group of materials.

DR. NORMAN: I give up.

MS. JEFFRIES: Could I say something about--you keep using the words "determining safety and effectiveness." What the panel is supposed to do is determine what class,

what level of control, will allow a reasonable assurance of safety and effectiveness. You may not be able to determine, you know, the actual safety and effectiveness.

DR. GLOWACKI: Yes, that's what I mean.

MS. JEFFRIES: Okay.

DR. GLOWACKI: Sorry for the shorthand.

MS. JEFFRIES: I just want to make sure we know what we're talking about.

DR. GLOWACKI: That's what I mean.

MS. JEFFRIES: Okay.

DR. ROBERTSON: All right, so we'll come back and vote, but those were the arguments and 1(c) was the same, III and III. So your recommendation, Dr. Glowacki, was that 1(c) as it presently stands, which is the load-bearing, is a III?

DR. GLOWACKI: That's correct.

DR. ROBERTSON: And would you have the same problems there as well?

DR. NORMAN: They have been resolved.

DR. ROBERTSON: All right, and do you want to now try to add, Dr. Glowacki, another category, like a 1(d), which does not include periodontal defects, but does include using it as an expander?

DR. GLOWACKI: Yes. It would be "A ceramic,

polymeric or composite device for us as an extender of fresh autogenous bone graft in filling osseous defects."

DR. ROBERTSON: Mark?

DR. PATTERS: Okay.

DR. ROBERTSON: Okay.

DR. PATTERS: Because the other definition would say used in a load.

DR. ROBERTSON: Yes.

DR. ROBERTSON: And osseous defects--you don't have problems with a periodontal defect being an osseous defect?

DR. PATTERS: Yes, I do.

DR. ROBERTSON: Yes, so can we--

DR. GLOWACKI: Non-periodontal osseous defect.

DR. PATTERS: Okay.

DR. ROBERTSON: I think non-periodontal osseous defects would be all right. We do know what happens if you put fresh autogenous bone next to a root. The root goes away. And that would make it crystal clear.

DR. GLOWACKI: Yes, and in terms of the special controls as well, the indications for use labeling, and all of that--that can be further refined to avoid using "in periodontal defects" or some such language.

DR. ROBERTSON: Okay, and that 1(d) then would be

class what?

DR. GLOWACKI: I would recommend Class II.

DR. ROBERTSON: II, and the special controls then would be as we see them, voluntary standards, guidance documents, training.

DR. GLOWACKI: Training would be key to that if it was with the fresh autogenous bone.

DR. ROBERTSON: Good. All right.

MS. SCOTT: Dr. Robertson?

DR. ROBERTSON: Yes?

MS. SCOTT: If I may ask a question for clarification, in that definition for use as an extender of fresh autogenous bone for filling non-periodontal osseous defects, would that include both oral and maxillofacial uses and non-load-bearing and load-bearing uses?

DR. NORMAN: I would, yes.

MS. SCOTT: Okay.

DR. ROBERTSON: Good.

DR. STEPHENS: Extraction sites.

DR. ROBERTSON: Oh, that's a good question. What about extraction sites? If you put extraction sites in there, we're going to be back in trouble.

DR. GLOWACKI: Yes. Certainly, not in this case, it would not be--

DR. ROBERTSON: Because you have included extraction sites specifically in the other places where you've had a III, this does include extraction sites.

DR. GLOWACKI: Haven't we finessed extraction sites all along the way deliberately?

DR. ROBERTSON: Yes. Good, okay. Are you ready, Julie, or should we move on to have a--

DR. GLOWACKI: Well, I'm trying to speak and write at the same time.

DR. ROBERTSON: Why don't you write so that you have them for the record quite clearly and you'll be comfortable with them, and we'll come back and formally make the motions and do our thing there?

Why don't we go on, Mark, to the 2, then, and 3?

DR. PATTERS: Very well. Taking a similar approach to what Dr. Glowacki took, I've tried to simplify this somewhat, but not completely along the lines of the possible classification that Ms. Kalbach showed, but not identically.

We've all agreed that there will still be two types, resorbable barriers and non-resorbable barriers, and I would propose--the first indication is for the filling of periodontal defects, which is similar to as it's shown presently in 3(a) and 4(a). I don't think those have to

change. Are you with me?

DR. ROBERTSON: I'm listening.

DR. PATTERS: Okay, but I'm going to propose just one other indication, and this one is much broader and I will try to say it. "For filling of localized osseous defects--for example, extraction, dehiscence, or fenestration defects, periapical defects, or defects associated with apicoectomy--and for localized augmentation of alveolar ridges."

DR. ROBERTSON: Okay, so that would be essentially 2(a).

DR. PATTERS: That would be 2--no--(b).

DR. ROBERTSON: (b), okay. (a) would be for use in periodontal defects.

DR. PATTERS: Period, right.

DR. ROBERTSON: Period. And (b) would be that sentence which you just read.

DR. PATTERS: Yes.

DR. ROBERTSON: Okay.

DR. PATTERS: Should I read that again?

DR. ROBERTSON: Yes.

DR. PATTERS: Okay. "For filling of localized osseous defects--for example, extraction, dehiscence or fenestration defects, periapical defects, or defects

associated with apicoectomy"--that's the end of the "for example," "and localized augmentation of alveolar ridges."

DR. ROBERTSON: Okay.

DR. STEPHENS: Mark, is there going to be a (c) for non-load-bearing areas? We'll leave that out completely or roll that into this one?

DR. PATTERS: No.

DR. STEPHENS: Okay.

DR. PATTERS: I'm not going to deal with the issue of load-bearing and non-load-bearing because then we have some great difficulties between resorbable and non-resorbable if we do that. So I'd just like to put them together, and I will tell you my recommendation will be that 2(a) and 3(a) will be Class II, with special controls of guidance documents. For 2(a), we need labeling as the indication of the time point for removal of the device. And for 2(b) and 3(b), I will also recommend those as Class II, but, in addition, they will have the special controls of clinical studies.

DR. ROBERTSON: Okay, so we have 2(a) and (b) having to do with the non-resorbable barriers and 3(a) and (b) having to do with the resorbable barriers as you read them.

DR. PATTERS: Correct.

DR. BOUWSMA: Did you list training, also?

DR. PATTERS: Yes. I'm sorry. Training for both.

DR. ROSAN: What were the clinical studies supposed to do in this? I thought clinical studies were for safety and effectiveness, and that got Class III, and Class II could only be compared to a predicate.

DR. PATTERS: As I understand, the clinical studies for a Class II device try to show that it is substantially similar to the predicate device. Is that not correct?

DR. ROSAN: That's right.

DR. PATTERS: And that's what they would have to do.

DR. ROBERTSON: When there is a new thing.

DR. PATTERS: You see, there are likely to be many new devices, since these polymers--there's a million ways to make them and there will be new ways next month and next year. How fast they resorb, how they resorb, what the end products of their resorption are, et cetera, are all important issues and they will need to have clinical studies and animal studies as well, I would guess, to show equivalence to the predict device, which are the existing ones.

DR. ROBERTSON: All right. Does everybody

understand? Any further discussion there?

DR. PATTERS: Judy?

DR. GLOWACKI: Well, I was assigned a task, so I didn't hear a word you said.

DR. PATTERS: We had collaborated on that and it worked out very well, didn't it?

DR. GLOWACKI: Yes, but let me then ask some questions that you probably already answered. In terms of the resorbable, did you say that there was specific information available for writing up the special controls for what the rate of resorption needed to be in order to have a reasonable assurance of safety and effectiveness.

DR. PATTERS: Yes. I think the FDA has already laid those out for the existing devices.

DR. GLOWACKI: I'm not talking about the periodontal defects. Didn't you put in--you've lumped together all of these other indications. Are those available for the other indications.

DR. PATTERS: I'll have to ask--

DR. GLOWACKI: Use with endosseous implants and--

DR. PATTERS: No, no. There were no endosseous implants in anything that I said.

MR. HLAVINKA: The only criteria guidance we have now for the resorbable is to aid in the healing of

periodontal defects, and that's it.

DR. PATTERS: For the resorbable?

MR. HLAVINKA: For the resorbable, that's correct.

DR. GLOWACKI: So, then, I'm sorry. I didn't hear how much of these terms in this box you added into periodontal defects.

DR. PATTERS: I didn't add anything into periodontal defects. That sits by itself as an indication. The second indication is "Filling of localized osseous defects--for example, extraction, dehiscence and fenestration defects, periapical defects, and defects associated with apicoectomy"--end "for example"--"and for localized augmentation of alveolar ridges." I was not satisfied that there's compelling evidence in the use of these membranes with endosseous implants and I did not include that in the indication.

DR. GLOWACKI: So would that be something that ought--yes, Mel?

MS. JEFFRIES: I have a question about the resorbable devices used in these localized sites. Is that a commercial pre-amendments use? If so, you cannot classify it. These have to be pre-amendments devices.

DR. PATTERS: I'm sorry. I didn't understand. Would you say that again?

MS. JEFFRIES: Have there ever been devices, resorbable devices, cleared for these uses in extraction sites, dehiscence, et cetera? If there haven't, there's no pre-amendments device and you can't classify it. They're automatically in Class III.

DR. PATTERS: Now, you're really confused me because I understood that pre-amendment device was not our issue. We were setting the pre-amendments devices.

MS. JEFFRIES: Well, there has to be one somewhere in the background. I mean, if we've never had a 510(k) approved for one of these devices, we wouldn't have anything to compare it to.

MR. ULATOWSKI: You're not creating devices. You're reflecting upon devices that have been commercialized prior to '76, or equivalent to those commercialized products for whatever indication. There are products also that are now used for certain uses, but they've never been submitted for clearance or commercialized for certain purposes.

DR. PATTERS: And therefore we cannot use the data?

MR. ULATOWSKI: Therefore, they're not subject to the classification process.

DR. PATTERS: But can we use the data to suggest a classification, data from the use of such devices?

MR. ULATOWSKI: Well, the indication would not be subject to classification, those indications that are not, as Mel mentioned, pre-amendments or equivalent to pre-amendments claims devices.

DR. PATTERS: I think I need to defer to the Chairman because I'm lost now.

DR. ROBERTSON: Well, I'd defer, actually, to Pam, who got--I mean, we, in fact, had membranes, and I remember actually having this discussion once before because of the grid we had set up, and we had all these indications on the grid and we included those indications for membranes, as well as others. And we went ahead and used them and classified them because either the literature or manufacturers had suggested that as a use.

MS. SCOTT: For the non-resorbable membranes, they had been cleared for the filling of periodontal defects and for filling of intraosseous gaps, voids and clefts, and for alveolar ridge augmentation. However, as you recall, at the last panel meeting, and if you look at the table for the resorbable membranes, we did not include the indications related to intraosseous gaps, voids and clefts, or augmentation of the alveolar ridge or fresh--

DR. ROBERTSON: Because you had not gotten any indication from the one company at that time that had made

an application for that as among its uses, right?

MS. SCOTT: Because the resorbables hadn't been cleared for those indications and only for--

DR. ROBERTSON: So, in fact, they're right, and until such time as FDA has to do that, we need to change the resorbable, which is 3(b), I guess, to reflect the fact that those indications are not in our purview at the moment.

DR. ROSAN: What does that mean?

DR. PATTERS: There is no 3(b).

DR. ROBERTSON: That's right. There is no 3(b). That's what that means, and we'll have a 3(b) eventually.

MR. ULATOWSKI: It doesn't impede us from reviewing these products as substantially equivalent later on down the road.

DR. ROBERTSON: That's correct, right.

DR. PATTERS: So what it means here is unless someone has asked for that and been granted it, there's no-- we cannot consider it. There is no predicate device.

DR. ROBERTSON: That's correct.

DR. PATTERS: Okay, but that doesn't preclude someone tomorrow from asking for that.

DR. ROBERTSON: Absolutely.

DR. PATTERS: Right.

DR. ROBERTSON: And in addition to that, staff has

heard our discussion and has listened and will use that discussion to guide them in at least their initial consideration.

MR. HLAVINKA: We could certainly evaluate these under 2(b). It's just a new material that the predicate device has been identified. The only difference would be the absorbability.

DR. ROBERTSON: Right, so 3(b) went away.

DR. PATTERS: I stand educated.

DR. ROBERTSON: Good. Now, what we are going to have do now is--

DR. PATTERS: Mr. Chairman?

DR. ROBERTSON: Yes?

DR. PATTERS: The last issue is whether there should be an indication for use with endosseous implants--I did not specify use with endosseous implants in (b)--whether there should be a (c) indication.

DR. GLOWACKI: Has it been cleared?

DR. PATTERS: I don't believe it has been cleared, but I'm not--

MR. HLAVINKA: For use with endosseous implants, there is no predicate device for use with any endosseous implant. Currently, endosseous implants are pre-amendments Class III, so we would probably look at this as an accessory

to a Class III device, which would make it Class III.

DR. PATTERS: You simplified it.

DR. ROBERTSON: Good. Any other concerns, questions, confusion?

[No response.]

DR. ROBERTSON: Well, what we are now going to do is we're going to go through--and I'm going to ask you whether you want to do that now or whether you want to do that tomorrow morning--we're going to go through each of these. We're going to read it so it's in the record. We're going to vote on acceptance by the group as a recommendation to FDA. The question is do you want to go through that now or do you want to wait until tomorrow morning.

DR. GLOWACKI: I wasn't going to be able to be here tomorrow morning, so I ask the indulgence of the committee to do it now.

DR. ROBERTSON: Then let's do it.

MR. ULATOWSKI: Mr. Chairman, there's more to the process, maybe, than you may think. If you've created a new group or you're changing the classification from before, then you have to go through the entire process of these sheets and that whole business that you went through before in filling out those things.

DR. ROBERTSON: Well, why don't we go through it

kind of informally and then tomorrow we'll do the formal stuff? How is that, because I'd like to hear as much from Dr. Glowacki before she leaves as I can?

So let's go through each of the groups, 1(a), 1(b), 1(c), and 1(d), then 2 and 3. Read them carefully to us, Julie. Pam, you need to write along with her so we're sure we have the language right in case we lose something in the translation. And then you can leave that, actually, with Carolyn so we have a copy. Good.

So why don't you start with 1(a)?

DR. GLOWACKI: I wrote out the definitions, and please help me and listen carefully because I may have omitted some of the phrases from the non-repeating portions.

1(a): "A ceramic, polymeric or composite bone-filling device for use in the filling of periodontal defects. The device may be a resorbable or non-resorbable material that is naturally or synthetically derived, or composed of a single polymer, copolymers or composites of two or more materials of a different type or phase. These may be in granular, mesh or solid form. This category does not include tricalcium phosphate granules."

DR. ROBERTSON: Fine. Recommended class?

DR. GLOWACKI: II.

DR. ROBERTSON: And special controls?

DR. GLOWACKI: As before.

DR. ROBERTSON: Voluntary standards, guidance documents, and training. Good.

DR. GLOWACKI: 2(b), definition--

DR. ROBERTSON: 1(b).

DR. GLOWACKI: I'm sorry; 1(b).

DR. ROBERTSON: Right.

DR. GLOWACKI: "A ceramic, polymeric or composite bone-filling device for use alone in filling bone defects and/or augmentation of the alveolar ridge in the non-load-bearing maxillofacial region." Then I just dittoed out the paragraph from above. "The device may be a resorbable or non-resorbable material that is naturally or synthetically derived, or composed of a single polymer, copolymers or composites of two or more materials of a different type or phase. These may be in granular, mesh or solid form." And then do we repeat that it's non-tricalcium phosphate all the way down, because you didn't in the original grid, Pam?

MS. SCOTT: That could be stated in the general device group.

DR. GLOWACKI: Okay. 1(c)--

DR. ROBERTSON: Recommended class?

DR. GLOWACKI: III.

MS. SCOTT: Could you repeat the first part of

that?

DR. GLOWACKI: "A ceramic, polymeric or composite bone-filling device for use alone in filling bone defects and/or augmentation of the alveolar ridge in the non-load-bearing maxillofacial region."

DR. TYLENDA: And the title of this device is ceramic, polymeric and composite bone-filling device.

DR. GLOWACKI: "Or." We're using "or," not "and."

1(c): "A ceramic, polymeric or composite device for use alone in the repair of bone defects and/or augmentation of the alveolar ridge in load-bearing regions"--I left out "maxillofacial"--"in load-bearing sites in the maxillofacial region. The device may be a resorbable, non-resorbable," ditto from above.

DR. ROBERTSON: Good, and recommended class?

DR. GLOWACKI: III.

DR. ROBERTSON: And 1(d)?

DR. GLOWACKI: "A ceramic, polymeric or composite device for us as an extender of fresh autogenous bone graft in filling load-bearing and non-load-bearing osseous defects in the maxillofacial region. The device may be," ditto from above. The recommendation is for Class II.

DR. ROBERTSON: Somebody may argue--

DR. GLOWACKI: It's my recommendation.

DR. ROBERTSON: --that if you classified 1(b) and 1(c) as III and all you did was take some hip marrow and threw it in there and mixed it up and then stuffed it in the same areas, how could you get it to be II? Why wouldn't--

DR. GLOWACKI: Because there's an enormous amount of information available on the effectiveness and safety--

DR. ROBERTSON: Of those combinations?

DR. GLOWACKI: --of those materials used in combination, and one could define the size of the defect, the nature of the population that I feel one can't do for 2(b) and 2(c).

DR. ROBERTSON: Because they are used alone?

DR. GLOWACKI: Correct.

DR. ROBERTSON: I think that's an important point. Good.

2(a)?

DR. PATTERS: 2(a) is--

DR. ROBERTSON: You can listen now, Julie.

DR. PATTERS: --"A non-resorbable barrier or membrane for use in periodontal defects, and that is a naturally or synthetically device that is intended to function as a barrier that allows selective tissue in-growth to aid in the filling and repair of periodontal defects. This device is intended to be removed." That's what we had

last time.

DR. ROBERTSON: Recommended class?

DR. PATTERS: II.

DR. ROBERTSON: And special controls?

DR. PATTERS: Same as before, guidance documents, labeling to indicate time of removal, training.

DR. GLOWACKI: Dr. Robertson, I'd like to ask Dr. Patters if it makes any sense, as I was reviewing this material before coming, whether there ought to be specific warnings for the patient in the labeling about signs of dehiscence or infection prior to the scheduled time of removal, or is that something that the periodontist always does with the patient?

DR. PATTERS: I think there are specific warnings to all of these materials regarding loss of the material or infection.

DR. ROBERTSON: I think it's a good point.

DR. STEPHENS: I think that's part of the informed consent for the procedure.

DR. ROBERTSON: Yes. Good.

2(b)?

DR. PATTERS: 2(b) is "A non-resorbable barrier or membrane for use in the filling of localized osseous defects and localized augmentation of the alveolar ridge, and that's

a device that is naturally or synthetically derived and is intended to function as a barrier to allow selective tissue in-growth for the filling of localized osseous defects or the localized augmentation of the alveolar ridge."

Now, where do you want the "for example?" Do we need the "for example?"

DR. ROBERTSON: I don't think so.

DR. PATTERS: Very well, okay. "These devices are intended to be removed." So osseous defects then can be interpreted to be periapical defects.

DR. ROBERTSON: Right.

DR. PATTERS: Why don't we then say "non-periodontal osseous defects," as we've done in--

DR. ROBERTSON: Good.

DR. PATTERS: That ought to take care of it. II.

DR. ROBERTSON: And then--

DR. PATTERS: Same special controls.

DR. ROBERTSON: Same special controls, and then we have 3(a), which was the same as--

DR. PATTERS: Same as before. Do you want me to read it, the same as it was before?

DR. ROBERTSON: Yes.

DR. PATTERS: "A resorbable barrier or membrane for use in filling periodontal defects. It is a device that

is naturally or synthetically derived and is intended to function as a barrier to allow tissue in-growth to aid in the filling and repair of periodontal defects." We would recommend Class II, with the same special controls of guidance documents and training.

DR. ROBERTSON: Good. Are we all clear and comfortable? Yes?

DR. BOUWSMA: A question. 4(a), the non-resorbable barrier--would that serve as a predicate device for a resorbable barrier, similar functions?

DR. PATTERS: Apparently not, since there's no 3(b). So, apparently, 3(a) was not the predicate device for 3(b), I assume.

MR. HLAVINKA: But there is no predicate for 3(b), but there are predicates for 2(b). So, yes, we could use the non-resorbable.

DR. ROBERTSON: That was the question.

DR. BOUWSMA: So if that's the case, why not just take resorbable, non-resorbable out of those definitions and not address that?

DR. PATTERS: I'm uncomfortable with that because the non-resorbables have to be removed and that requires some determination by the manufacturer as to the appropriate time post-insertion to remove them, and additional studies

have to be done to determine the appropriate time.

DR. BOUWSMA: But wouldn't that come under the special controls for that particular device which would be included in the labeling and everything, as you specified?

DR. PATTERS: I'm always confused in that area, but my gut feeling is, no, that these would be special studies that would have to be done for non-resorbable membranes which would not be done for resorbable membranes. So I see them as separate devices, but that's just my opinion.

DR. ROBERTSON: There's some advantage for keeping them separate.

DR. BOUWSMA: I mean, if there's an advantage, I'm all for it, but it just seems like--

DR. ROBERTSON: The 2(b) is sitting there serving to help resorbables, should they come.

DR. BOUWSMA: Okay.

DR. ROBERTSON: Good.

DR. GLOWACKI: Dr. Robertson, I was just reminded I forgot to insert the term "non-periodontal" in front of "osseous defects" in definition 1(d), so will the record correct that, please?

DR. ROBERTSON: And did you put it in your--good, so we have it. Great.

We've done really good here. I'm at your pleasure, but my recommendation is that we seem to be content--it's probably useful for us to have an evening to think about it--that at 8:30 tomorrow we go through the process, and you'll be here to help us do that, I assume. Somebody will be here to help us do that to, in fact, make sure--we made some minor--actually, just in one case, I think, we made some classification changes that we need to redo the paperwork on. Then we do the formal motions and we'll have it done. The fact that Julie won't be here as a voting member won't--

DR. GLOWACKI: I can't cast my vote now?

DR. ROBERTSON: No, says the--but we'll have enough voting members. I'll represent you.

Good. So do I hear a motion for adjournment until 8:30 tomorrow morning?

DR. ROSAN: So moved.

DR. ROBERTSON: All in favor, say aye.

[A chorus of ayes.]

DR. ROBERTSON: Opposed?

[No response.]

DR. ROBERTSON: Whereupon, at 6:09 p.m., the meeting was adjourned, to reconvene at 8:30 a.m., Wednesday, August 9, 1995.]